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Is Two a Trend? Recent Government Resolutions Hint at Sunshine Act Enforcement

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Since the passage of the Sunshine Act (now more formally referred to as the Open Payments Program) and the first Open Payments reports submitted in 2014, there have not been any public-facing, government enforcement actions or settlements related to the Open Payments Program. Recently, however, the Department of Justice ("DOJ") has expressed interest in parallel settlements that resolve alleged violations of the Anti-Kickback Statute ("AKS"), False Claims Act ("FCA"), and the Open Payments Program ("Program"). We are finally seeing the federal government issuing penalties to companies for alleged non-compliance with the Program's reporting requirements. Under the Open Payments Program, "reporting entities," including certain pharmaceutical and medical device companies, must annually report certain transfers of value made to "covered recipients" (e.g., U.S.-licensed health care providers ("HCPs") and teaching hospitals), regardless of where the associated activity occurs.

The Two Recent Open Payments Program Settlements

Most recently, on Wednesday, May 19, 2021, the DOJ announced a settlement agreement with a French medical device manufacturer and its U.S.-affiliate to resolve alleged violations of the AKS, FCA, and Open Payments Program. The federal settlement resolves allegations that the medical device manufacturer provided items of value in the form of meals, alcoholic beverages, entertainment, and travel expenses to U.S.-licensed physicians at events surrounding the Scoliosis Research Society's September 2013 Congress in Lyon, France. The DOJ alleged that the manufacturer provided the benefits to induce the physicians to purchase or order its spinal devices, which resulted in the submission of false payment claims to federal healthcare programs.

To resolve these allegations, the medical device manufacturer agreed to a $2 million settlement with the DOJ and participating states. First, the company agreed to pay $1 million to resolve civil whistleblower allegations that the company violated the AKS and FCA by entertaining U.S.-based physicians during the 2013 conference in France. The second $1 million was earmarked to resolve allegations that the company violated the Open Payments Program by failing to fully report those physician-entertainment expenses to the Centers for Medicare & Medicaid Services ("CMS"). This civil settlement also resolves the claims brought under the *qui tam* whistleblower provisions of the FCA statute, which was filed in the Eastern District of Pennsylvania.

The May 2021 settlement comes only seven months after the very first Open Payments Program settlement with another medical device maker based in Minnesota. The DOJ alleged the medical device company paid for more than one hundred events, over a nine-year period, at a South Dakota

neurosurgeon's restaurant. It was alleged that the company made these payments—which it allegedly failed to accurately report under the Open Payments Program—to induce the neurosurgeon to use its medical device products (e.g., implantable devices used to deliver medication to patients). In October 2020, the company agreed to a $9.2 million resolution, with $8.1 million to resolve allegations that it violated the FCA by paying kickbacks to induce the neurosurgeon to use its products, and $1.1 million to resolve allegations that it violated the Open Payments Program by failing to accurately report payments it made to the neurosurgeon to CMS. According to the Former Department of Health and Human Services ("HHS") Deputy General Counsel and Former CMS Chief Legal Officer, Brenna E. Jenny, who was quoted in the DOJ's October 2020 press release regarding the settlement, "CMS's Open Payments Program is intended to promote transparency and accountability in the healthcare system." Jenny added, "Manufacturers that misreport their financial relationships with healthcare providers erode the integrity of the Open Payments Program and will be held accountable," and "CMS looks forward to continued partnership with the Department of Justice to resolve allegations of manufacturers skirting their Open Payments obligations."

The above two settlements are the first public enforcement actions to resolve alleged non-compliance with the Open Payments Program. Unsurprisingly, the settlements follow the Senate Finance Committee's March 19, 2019 letter to the Office of Inspector General ("OIG") for HHS and CMS, which asked both agencies to investigate non-compliance with the Program's requirements and to pursue enforcement. The letter concludes with the statement that Senators Grassley (one of the architects behind the Sunshine Act) and Wyden "look forward to working with the Administration to ensure that the Sunshine Act is up-to-date and that the penalties for non-disclosure are implemented against bad actors who fail to report."

Recent Open Payments Program Updates & Reminders

As of January 1, 2021, for the first time since its inception in 2013, the Open Payments Program reporting requirements have significantly expanded to now include new HCP / provider types (covered recipients), including U.S.-licensed: (1) physician assistants; (2) nurse practitioners; (3) clinical nurse specialists; (4) certified registered nurse anesthetists and anesthesiologist assistants; and (5) certified nurse-midwives. These additions are in response to statutory changes outlined in the SUPPORT Act.

Tracking, collecting, validating, and reporting information related to reportable transactions is already a complex process for life sciences companies, and this addition to the Program's reporting requirements will increase the complexity; necessitating updated internal systems, data management policies, and trainings on the recent changes. Accordingly, as we approach the mid-year mark (and two months after the 2020 report submissions), provided below are some high-level considerations and reminders for companies and internal stakeholders responsible for complying with the Open Payments Program.

- Develop, Enhance, and Pressure Test Compliance Controls. Check and, as needed, develop new or enhance existing written standards regarding the Open Payments Program and other transparency requirements (i.e., at state and local level). Written standards would include policies, standard operating procedures (SOPs), work instructions, gatekeeper documents, and additional material / tools that help streamline and ensure compliance (e.g., requiring certain fields in the field force's customer relationship management system; identifying individuals and entities as "reportable" in the accounts payable system).

- Engage Internal Stakeholders & Affiliates to Develop a Streamlined and Reliable Process Flow. From the field force to sales / commercial operations to finance to vendors to company affiliates

to compliance, all individuals involved in the transfer of value process should receive detailed training on the company's processes and should be involved in periodic discussions to ensure the company's process flow is seamless. This is particularly important for multinational organizations where ex-U.S. affiliates engage and provide transfers of value to HCPs. By providing training upfront and by periodically checking in, companies can help ensure that the data required is timely and accurately captured, validated, and submitted to those responsible for report submissions—and that companies have enough time to assess anomalies, questionable transactions, and any other payments or transfers that may warrant further attention.

- Monitoring & Auditing. Like many processes within the life sciences industry, periodic (e.g., annually, quarterly, real-time) monitoring and auditing are essential for an internal process to operate effectively and efficiently. Through monitoring and auditing efforts, companies can identify gaps in the data tracking, capture, and validation processes that could jeopardize the ability to submit a timely and accurate Program report. In addition, through these efforts, companies will have an opportunity to identify potential red flags or deviations from established parameters (e.g., exceeding threshold limitations, little or no reportable payments by a sales representative, incomplete or missing transfer of value information).

Conclusion

With continued scrutiny regarding HCP interactions, and the above-referenced settlements, life sciences companies must continue to accurately track, collect, validate, and report certain expenses and transfers of value to HCPs and certain organizations—in the U.S. and around the world (e.g., patient groups under the "French Sunshine Act"). And with large penalties associated with non-compliance (e.g., $10,000 to $100,000 per expense report line item[1]), and now concrete examples of government enforcement, companies should ensure that their processes for compliance with the Program's requirements are adequate. This is especially critical as the industry starts to see the DOJ simultaneously enforce Open Payments Program violations alongside AKS and FCA violations.

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If you have any questions concerning these developing issues, please do not hesitate to contact any of the following Paul Hastings New York lawyers:

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[1] The total amount of civil monetary penalties imposed on each applicable manufacturer or group purchasing organization (regardless of whether the applicable manufacturer was a part of a consolidated report) with respect to knowing failures to report in an annual submission of information will not exceed $1,000,000 as adjusted annually under 45 CFR part 102.